OCT 18 2012

Attachment III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K120420

1. Date of Submission: 17 OCT 2012

2. Sponsor
   Shanghai Double-Dove Industry Co, Ltd.
   No.1888 Huhang Road, Fengxian Economic Zone
   Shanghai, 201400, China

   Establishment Registration No.: 3004416208

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   Vice General Manager
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Sterile Blunt for Single Use
   Proposed Device Model: Blunt Fill Needle and Blunt Plastic Cannula

   Classification: II
   Product Code: FMI
   Regulation Number: 21 CFR 880.5570
   Review Panel: General Hospital

Intended Use Statement:

The Sterile Blunt for Single Use includes two models, which are blunt fill needle and blunt plastic cannula.

The blunt fill needle is used in conjunction with a syringe to penetrate the vial/ampoules stopper intended for injection or aspiration of fluid.

The blunt plastic cannula is used in conjunction with a syringe to access the pre-slit septum covering injection sites on I.V. System intended for injection or aspiration of fluid.

5. Predicate Device Identification

510(k) Number:K102328
Product Name: Blunts
Manufacturer: Shan Dong Wei Gao Group Medical Polymer Co., LTD

6. Device Description

The proposed device, Sterile Blunt for Single Use, includes two models, which are blunt fill needle and blunt plastic cannula.

The blunt fill needle consists of a stainless steel needle tube, a hub and a sheath. It is used to penetrate the vial and/or ampoules stopper intended for injection or drawl fluid. It is not intended to access the injection site on I.V. System.

The blunt plastic cannula consists of molded plastic blunt tipped cannula, a hub and a sheath. It is used to replace hypodermic needles to prevent from the unintended injury by metal needle.

Both two models are available in either EO sterilized or Radiation Sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The proposed device is sealed in a sterility maintenance package to maintain its sterility during its shelf life of three (3) years.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 9626:1991/Amendment 1:2001, Stainless steel needle tubing for the manufacture of medical devices.

ISO 7864:1993, Sterile hypodermic needles for single use.

ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements.

ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

ISO 10993- 4:2002/Amd 1:2006, Biological Evaluation of Medical Device. Part 4: Selection of test for Interactions with Blood.

ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity. 2-153

ISO 10993-7:2008, Biological evaluation of medical devices —Part 7: Ethylene oxide sterilization residuals

ISO 10993-10: 2002/Amd. 1:2006(E), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1.

ISO 10993-11: 2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.

ISO 11135-1: 2007 Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

USP 34:2011, <85> Bacterial Endotoxins Test.

ASTM F1140-07, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.

ASTM F88-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

ISO 11137-2: 2006, Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose.

8. Substantially Equivalent Conclusion

The proposed device, Sterile Blunt for Single Use, has same intended use, configuration, operation mode with those of the predicate device, Blunts (K102328). The materials are different, the biocompatibility test and leachable substance analysis demonstrated that the materails used for manufacturing of proposed dveice are safe and accpetable. The bevel of the proposed device is identical to that of the predicate device, while the gauges of proposed and predicate device is different. The physical performance test results submitted demonstrated the proposed device complied with the referenced standards with different gauge of the predicate device. The proposed device is available in EO sterilization or Radiation sterilization, the predicate device is only avaiable in radiation sterilization. Various tests, including biocompatibility, perfromance, package, endotoxin tests demonstrated that the both EO sterilization and Radiation sterilization proposed device complied with acceptance criteria. In addition, both of the proposed and predicate device could achieve same Sterility Assurance Level (SAL)

Therefore, the proposed device, Sterile Blunt for Single Use, is determined to be Substantially Equivalent (SE) to the predicate device, Blunts (K102328), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shanghai Double-Dove Industry Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai, CHINA 200237

OCT 18 2012

Re: K120420
Trade/Device Name: Sterile Blunt for Single Use
Model: Blunt Fill Needle, Blunt Plastic Cannula
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 30, 2012
Received: September 7, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

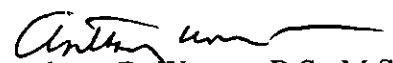
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120420

Section II Indications for Use

510(k) Number:
Device Name: Sterile Blunt for Single Use
Model: Blunt Fill Needle, Blunt Plastic Cannula

Indications for Use:

Sterile Blunt for Single Use includes two models, which are blunt fill needle and blunt plastic cannula.

The blunt fill needle is used in conjunction with a syringe to penetrate the vial/ampoules stopper intended for injection or aspiration of fluid.

The blunt plastic cannula is used in conjunction with a syringe to access the pre-slit septum covering injection sites on I.V. System intended for injection or aspiration of fluid.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rhd C Chan 10/12/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices.

510(k) Number: K120420